inches, usually in the range from about 0.2 to 5 inches and more usually in the range from about 0.5 to 3 inches. The weight of the subject device is usually in the range from about 0.02 to 10 pounds and more usually in the range from about 0.04 to 5 pounds, but in most cases is less than about 2 pounds. The proximal end of the device, *i.e.*, the end of the device which is in close proximity to or in direct contact with the skin when in use, typically includes a proximal orifice, where such an orifice usually has a diameter less than about 5 millimeters, and is in the range from about 1 to 4 millimeters, and more usually in the range from about 1 to 2 millimeters.

[00106] Typically, the visible surface of the unit will include a display or screen on which messages, instructions, error warnings, and most importantly, results, *i.e.*, whether a site is suitable and/or the concentration of an analyte, may be displayed by means such as liquid crystal displays, as are known in the art. Such information may be conveyed by alphanumeric digits or units or pictorial icons. In certain embodiments, an audio means may also be present in or on the device for audibly conveying information to the user. Additionally, the subject device may include a power switch for manually activating the device.

I. SITE FLOW ELEMENT

[00107] As described above, in certain embodiments of the subject invention, the housing includes at least one site flow characterization element which characterizes the flow of a potential site, *i.e.*, the flow rate or velocity of the site. A wide variety of elements or components may be employed to determine the flow characterizations of a particular sampling site, where particular embodiments of interest will now be described.

A. Temperature Characterization Element

[00108] In certain embodiments, the flow characterization element includes an element capable of characterizing the temperature of a potential site. For example, a temperature element or sensor such as a thermocouple or the like may be employed, where such thermocouples are known in the art. Such a temperature element may be in place of or in addition to, other elements used to characterize the flow of a site, such as the RBC characterization element described below, where one or more site characterization elements are capable of being activated at the same or different times, *e.g.*, a temperature

element is capable of being activated at the same or different time as a light detecting element, etc.

[00109] The temperature element of the present invention is one which is capable of measuring the temperature of the site, where such a temperature is an indication of the flow character of the site. In other words, the temperature of the skin increases as blood flow increases due to factors such as the velocity of the flow of fluid at the site.

[00110] Accordingly, the temperature sensor is capable of measuring infrared radiation or temperatures in the range from about 0 to 100°C, usually from about 10 to 75°C and more usually from about 10 to 50°C. Typically, the temperature element will be positioned in close proximity to the proximal aperture of the device or housing; however, other positions may be employed as well depending upon the configuration of the device, the particular temperature sensor used and the specific body area to be tested.

B. RBC Characterization Element

[00111] In other embodiments, the flow characterization element is an element capable of characterizing the RBCs of the site, e.g., RBC flux characterization. RBC characterization elements may be in addition to, or in place of, other flow characterization elements, as described herein. Where the RBC characterization element is in addition to other elements, the elements may be capable of being activated at the same or at different times.

[00112] Typically, an element configured to perform RBC characterization, e.g., RBC flux determination as described above, usually includes at least one light source capable of emitting light, usually coherent, single wavelength light, at a wavelength ranging from about 400 to 1200 nm, usually from about 450 to 800 nm such as a laser as is commonly known in the art, and a sensor or detector, typically a broadband sensor or detector, for detecting the intensity of light reflected from the RBCs. The at least one light source may thus include one or more: light emitting diode (LED), laser diode, light emitter, bispectral emitter, dual spectral emitter, photoemitter, photodiode, semiconductor die, or the like, and the detector may include one or more: photodiode, photoelectric receiver, photodetector such as a broadband photodetector, semiconductor die, or the like.

[00113] Examples of commercially available elements capable of RBC characterization or RBC flux characterization, e.g., Doppler flowmeters, adaptable for use with the

present invention include, but are not limited to, flowmeter models LD-5000 and LD-6000 manufactured by Medpacific of Seattle, WA; flowmeter models PF1, and models PF2 and PF3 manufactured by Perimed of Stockholm, Sweden.

The RBC characterization element may be operatively associated with a microprocessor under the control of a software program that is capable of processing signal from the site and determining the RBC character, e.g., RBC flux, or a statistically relevant value thereof, of the site based upon the measured intensities of reflected light and may also perform the steps necessary to compare such a RBC characterization value or measurement such as RBC flux value to a predetermined value or to RBC characterization values of various tested sites.

II. Sample Type Characterization Element

[00114] As mentioned above, the subject devices may also includes one or more sample type characterization element, where such an element is capable of characterizing a site as either primarily or generally (1) arterial/capillary, (2) venous or (3) interstitial fluid, and more specifically is capable of characterizing the type of sample at a site as either primarily or generally arterial/capillary, venous or interstitial fluid. A variety of elements may be used to characterize the type of sample at a site. For example, elements include those capable of characterizing the pulse of a site and/or characterizing the Hb of the site, as will now be described in grater detail.

A. Pulse Characterization Element

[00115] The pulse characterization element is an element capable of characterizing the pulse of a site. Pulse characterization may be in addition to, or in place of, other sample type characterization elements, as described herein. Where the pulse characterization element is in addition to other elements, the elements may be capable of being activated at the same or at different times.

[00116] Typically, an element configured to perform pulse characterization usually includes at least one light source capable of emitting light, usually coherent, single wavelength light at a wavelength from about 400 to 1200 nm, usually from about 450 to 800 nm such as a laser as is commonly known in the art, and a sensor, typically a broadband sensor or detector for detecting the intensity of light reflected from the RBCs. The light source may include one or more: light emitting diode (LED), a laser diode, a